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INTRODUCTION:

The purpose of the STEPS UP (**ST**epped **E**nhancement of **P**TSD **S**ervices **U**sing **P**rimary Care) trial is to compare centralized telephonic care management with preference-based stepped PTSD and depression care to optimized usual care. We hypothesize that the STEPS UP intervention will lead to improvements in (1) PTSD and depression symptom severity (primary hypothesis); (2) anxiety and somatic symptom severity, alcohol use, mental health functioning, work functioning; (3) costs and cost-effectiveness. We further hypothesize that qualitative data will show (4) patients, their family members, and participating clinicians find that the STEPS UP intervention is an acceptable, effective, and satisfying approach to deliver and receive PTSD and depression care.

STEPS UP is a six-site, two–parallel arm (N = 1,500) randomized controlled effectiveness trial with quarterly follow-up for 12 months comparing centralized telephonic stepped-care management to optimized usual PTSD and depression care. In addition to the existing PTSD and depression treatment options, STEPS UP will include web-based cognitive behavioral self-management, telephone cognitive-behavioral therapy, continuous RN nurse care management, and computer-automated care management support. Both arms can refer patients for mental health specialty care as needed, preferred and available. The study will use sites currently running RESPECT-Mil, the Initiating PI's existing military primary care-mental health services practice network, to access site health care leaders and potential study participants at the 6-study sites.

If effective, we expect that STEPS UP will increase the percentage of military personnel with unmet PTSD- and depression-related health care needs who get timely, effective, and efficient PTSD and depression care. Our real-world primary care effectiveness emphasis will prevent the Institute of Medicine's so called "15 year science to service gap." If successful, STEPS UP could roll out immediately, reinforcing and facilitating pathways to PTSD and depression recovery.

BODY:

During the first year of the project we have further developed and refined the STEPS-UP intervention building on materials from our proposal. The refinements include a web-based care management support tool, a nurse-assisted web-based cognitive behavioral self management tool, a structured telephonic cognitive-behavioral therapy approach, and a preference-based stepped care approach to primary care PTSD treatment sequencing. Additionally, we have refined the clinical trial design, recruitment plan, and assessment procedures and measures. In the third quarter, RAND completed the process of obtaining feedback on the STEPS UP intervention protocol from experts, and revisions were made to the protocol as necessary. The development of training manuals is underway, and is anticipated to be completed in the next 6 months. Over the last year of the study, subawards with the University of Washington and the Boston VA Research Institute (BVARI) were approved and finalized, and BVARI has also posted a request for proposals (RFP) and subsequently hired Boston Interactive, a web company that will develop and maintain the website for the web-based treatment. Additionally, a vendor contract with Previdence Corporation was developed and finalized.

We have coordinated regularly with the Human Research Protection Office (HRPO) to streamline the regulatory submission and approval process. To this end, we held a meeting with several representatives from WRAMC's Department of Clinical Investigation (DCI) and HRPO to determine the best way to proceed with IRB submission. The study protocol and consent form were submitted HRPO for preliminary review and to Walter Reed Army Medical Center for official review as the lead IRB. Both the University of Washington and BVARI have obtained preliminary IRB approval from their respective regulatory bodies to begin work on this project. RAND and RTI have also obtained IRB approval for start-up activities. Discussions are underway at RAND and RTI as to the extent of IRB review for the main clinical trial, given the multiple other reviews that will be taking place. Additionally, per the guidance of HRPO and DCI, we have decided to initiate an omnibus IRB agreement with each site IRB; these agreements are currently under development. We have also initiated the development of data use and sharing agreements between collaborators and other institutions. We are currently developing a strategy for obtaining feedback on the logistics of the clinical trial at two study sites; we anticipate obtaining this feedback in the next 1-3 months.

In addition to a kick-off conference call in the beginning of the year, study investigators have participated in multiple routine weekly conference calls and other communications as necessary to ensure timely completion of all tasks. We also convened a 1-day meeting in Washington DC on May 10, 2010, to work on measures. Members of the Scientific Advisory Board and Consumer Advisory Board have been confirmed and will be convened in the coming months. Several candidates for the Data Safety and Monitoring Board (DSMB) have been nominated and contacted; we anticipate confirming members of the DSMB in the next quarter. Because we are still in the early stages of the regulatory process, no intervention staff were hired. A website for the study was developed by RTI with input from the research team, to provide information for potential research participants such as a list of Frequently Asked Questions (FAQ), study site locations, and a brief description of the purpose of the study and its methodology. It also provides a single, integrated location for the team to share study-related documents (e.g., manuals, articles, progress reports, IRB materials, protocols), calendars, and contact information.

KEY RESEARCH ACCOMPLISHMENTS:

There are not yet any clear scientific findings resulting from this research as we are still undergoing regulatory review. Results are expected in January 2014.

REPORTABLE OUTCOMES:

A poster was presented at the 2009 USUHS Research Week in May, 2009 (see Appendix 1). Additionally, we submitted an abstract for a symposium presentation to the International Society of Traumatic Stress Studies (ISTSS) that was accepted for the November 2010 annual meeting in Montreal (see Appendix 2).

CONCLUSION:

There are no conclusions to report at this time, as we are still undergoing regulatory review.

REFERENCES:

None

APPENDICES:

Abstract for the May 2009 poster presentation at the 2009 USUHS Research Week (Appendix 1 and 2)

SUPPORTING DATA:

N/A

APPENDIX 1: USUHS Research Week Abstract

A Randomized Effectiveness Trial of a Systems-level Approach to Stepped Care for War-related PTSD

Charles C. Engel, MD, MPH (1,2), Robert M. Bray, PhD (3), Lisa Jaycox, PhD (4), Brett Litz, PhD, MA (5,6), Douglas Zatzick, MD (7), Terri Tanielian, MA (4), Donald Brambilla, PhD (8), Christine Eibner, PhD (4), Allen Dietrich, MD (9), Phoebe Kuesters, BA (2), Jurgen Unützer, MD, MPH (10), Wayne Katon, MD (10)

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Despite the significant prevalence of posttraumatic stress disorder (PTSD) among veterans returning from Operations in Iraq and Afghanistan, less than half of servicemembers who are referred for a specialty mental health assessment actually receive specialty mental health treatment. Systematic knowledge regarding access to care and quality of care delivered in civilian, VA, and military facilities for those who encounter barriers or difficulty is scant, and recent policy reviews have strongly questioned availability and quality of care. These problems of access and quality are major, overarching problems in war-related PTSD research. There are scientifically tested strategies from non-military settings and for other mental disorders to improve access to and quality of care; unfortunately, these strategies are unstudied in the military health system and for PTSD. The Department of Defense is funding this multi-institutional, multi-disciplinary research aiming to evaluate these systems-level strategies in a military setting. We will conduct an eight-site, two parallel arm randomized controlled trial with quarterly follow-up for 12 months comparing centralized telephonic stepped care management (TSCM) to optimized usual PTSD care. Along with usual PTSD treatment options, TSCM will include web-based self-management and telephonic cognitive-behavioral therapy augmentations. The study will also assess the cost-effectiveness of centralized TSCM relative to optimized usual care and perform qualitative analyses of patient perceptions of acceptability of, satisfaction with, and effectiveness of the TSCM intervention. By improving access to and quality of care, we expect to increase the percentage of personnel getting treatment and improve treatment outcomes.

APPENDIX 2: ISTSS Abstract

Improving primary care for US troops with PTSD and depression in military primary care clinics: RESPECT-Mil and STEPS-UP

Charles Engel, Lisa Jaycox, Robert Bray, Michael Freed; Brett Litz; Terri Tanielian, Doug Zatzick, Jürgen Unützer, Wayne Katon.

PTSD and depression are a serious problem for roughly 15% of U.S. military personnel returning from the conflicts in Iraq and Afghanistan. Stigma, fear of harm to career, and institutional barriers to mental health care in the military health system prevent many from seeking care. In 2007 the Army initiated RESPECT-Mil, a collaborative care approach to improving primary care recognition, treatment, and continuity of care for these conditions. RESPECT-Mil was rolled out to 15 Army sites (42 primary care clinics) and is now adding another 19 sites (53 clinics). In this presentation we will (1) describe the RESPECT-Mil model, (2) present data on program use to date, (3) outline feedback from implementers and providers, (4) discuss implementation logistics, barriers, and challenges, and (5) show how lessons to date are being used to develop and test a second generation model called "STEPS-UP". STEPS-UP incorporates new care manager strategies for engaging and motivating patients and helping determine treatment preferences; adopts a more comprehensive stepped treatment paradigm, adding a continuum of psychosocial management options; and uses distance modalities (Web, telephone) to maximize participation. A new multisite controlled trial will evaluate STEPS-UP versus RESPECT-Mil to determine whether STEPS-UP benefits will outweigh its unintended effects.